

## **Local AIDS Pharmaceutical Assistance (LPAP) Standards of Care**

### **Definition:**

The purpose of a Local AIDS Pharmaceutical Assistance Program (LPAP) is to provide therapeutics to treat HIV/AIDS or to prevent the serious deterioration of health arising from HIV/AIDS in eligible individuals, including measures for prevention and treatment of opportunistic infections. An LPAP is a program to ensure that clients receive medications when other means to procure medications are unavailable or insufficient. As such, LPAPs are meant to serve as an ongoing means of providing medications for a period of time.

### **Limitations:**

Local pharmacy assistance programs are not funded with AIDS Drug Assistance Program (ADAP) earmark funding.

LPAPs are not to take the place of the ADAP program.

LPAPs are not emergency financial assistance for medications

Clients cannot be enrolled in another medication assistance program for the same medication, excluding co-payment discounts.

Funds may not be used to make direct payments of cash/vouchers to a client.

No charges may be imposed on clients with incomes below 100% of the Federal Poverty Level (FPL).

Local AIDS Pharmacy Assistance Program (LPAP) do not dispense medications as:

- A result or component of a primary medical visit
- A single occurrence of short duration (an emergency)
- Vouchers to clients on an emergency basis

(Emergency Financial Assistance service category funds should be used for the above situations)

### **Services:**

The purpose of a Local Pharmaceutical Assistance Program (LPAP) is to provide therapeutics to treat HIV/AIDS or to prevent the serious deterioration of health arising from HIV/AIDS in eligible individuals including measures for prevention and treatment of opportunistic infections. Each Administrative Agency is required to either establish a LPAP Advisory Board or with a written agreement between the AA and the AA of another service area, may use an established LPAP advisory board in another HSDA or Part A jurisdiction to meet LPAP requirements (sample agreement located in Attachment 1). The LPAP Advisory Board will develop a formulary that meets the needs of the jurisdiction. There is no definitive list of medications that are to be included or excluded from a formulary as each jurisdiction

needs to determine what these are based on client need. Each LPAP Board must have a process in place to add or delete medications in a timely manner as the need changes.

## **Statement of Need:**

The Texas AIDS Drug Assistance Program (ADAP) has a limited formulary and limits income eligibility to 200% of the Federal Poverty Limit (FPL), with spend down adjustment to account for the cost HIV medications. Providers must first use patient and/or pharmaceutical assistance programs (PAP) prior to the use of LPAP. However, these programs may not fully meet the needs of clients with HIV-related medication needs because the full spectrum of HIV and HIV-related medications that may be prescribed to improve health outcomes may not be affordable or available via a PAP. The LPAP is needed to assist clients that have incomes above 200% of FPL, after spend down adjustment. LPAP is further needed to assist clients requiring long-term HIV and HIV-related medications that cannot be obtained through the Texas ADAP program or PAPs. The Texas ADAP must be accessed by eligible clients prior to using the LPAP. The LPAP may not duplicate services available through the Texas ADAP program. Clients needing long-term assistance with prescription medications shall be assisted with completing an ADAP application and, when applicable, PAP applications. If the medication is not on the Texas ADAP formulary and is not available through assistance programs, the client may be served with LPAP funds if the medication is on the LPAP formulary. If short-term medication assistance is required and a client is eligible, this need may be met with Emergency Financial Assistance (EFA) funds. Clients with insurance and other third-party payer sources are not eligible for LPAP assistance unless there is documentation on file that the medication is not covered by their prescription benefits.

Local AIDS Pharmaceutical Programs provide:

- HIV medications that are not included in the ADAP formulary
- Medications when the ADAP financial eligibility is restrictive
- Medications if there is a protracted State ADAP eligibility process (such as a wait list) and/or other means of accessing medications are not available (i.e., pharmaceutical company assistance programs)

Purchase of pharmaceuticals must be directly linked to the management of HIV disease that is:

- Consistent with the most current HIV/AIDS Treatment Guidelines
- Coordinated with the State's Part B AIDS Drug Assistance Program (ADAP)
- Implemented in accordance with requirements of the 340B Drug Pricing Vendor Program and/or Alternative Methods Project

LPAP can fund prescribed medications deemed medically necessary by a provider for medication not on the TMHP formulary for TMHP enrolled patients. Patients denied TMHP can also access funding through LPAP if other payer sources has been exhausted.

LPAP medication must be purchased at the lowest possible cost, such as the HRSA 340B/Prime Vendor or Alternative Methods Project Program pricing. Where possible clients need to obtain their medications through a 340B covered entity or pharmacy that is under contract with the 340B Program. Another alternative for purchasing medication is to establish a cost reimbursement system with pharmacies licensed to distribute medications in Texas. Contracts/Memorandums of Understanding (MOU) must be set up to purchase medications at wholesale or another below retail price.

All LPAP programs will use the statement of need and available standards of care to inform their services and will operate in accordance with legal and ethical standards. The importance of maintaining confidentiality is critical and all programs must comply with the Health Insurance Portability and Accountability Act (HIPAA) standards for information disclosure.

Over-the-Counter medications to include vitamins may be purchased with LPAP funds if the medication is listed on the LPAP formulary and the provider has deemed that the medication is needed for prevention and treatment of opportunistic infections or to prevent the serious deterioration of health.

Medications not included in the LPAP formulary cannot be purchased. The provider wishing to prescribe a medication not on the formulary shall make a request to the LPAP Board for approval.

## Personnel and Agency Standards

Agency Standards	Expected Practice
<b>Facility Licenses</b> Agencies dispensing medications shall adhere to all local, state and federal regulations and maintain current facility licenses required to operate as a pharmacy in the State of Texas.	Active pharmacy license is on site and is renewed every two years.  Pharmacies and pharmacy staff will adhere to the Texas State Board of Pharmacy rules and regulations.
<b>Private/Locally-Owned Pharmacies</b> If the owner of the pharmacy is not a Texas licensed pharmacist, the owner is consulting with a pharmacist in charge (PIC) or with another licensed pharmacist.	Documentation on file that a licensed pharmacist is consulting with the owner.
<b>Confidentiality Statements</b>	Signed confidentiality statements of staff are kept on file (HIPPA compliance)
<b>Storage of Medications</b>	Pharmacy shall maintain appropriate, locked storage of medications and supplies (including refrigeration) according to the State Board of Pharmacy regulations.
<b>Client Grievance Policy</b>	Pharmacy or medication site providing medications will have a policy and procedure in place for clients to voice complaints or grievances with services

Staff Qualification	Expected Practice
<p><b>Dispensing of Medications</b> Only authorized personnel may dispense/provide prescription medication.</p>	<p>Licensed pharmacists authorized by the Texas State Board of Pharmacy to dispense medications.</p> <p>Pharmacy technicians and other personnel authorized to dispense medications are under the supervision of a licensed pharmacist.</p> <p>A licensed nurse or practitioner designated by the pharmacist-in-charge (PIC) as supportive personnel may provide unit of use packaged medications.</p>
<p><b>Payer of Last Resort</b></p>	<p>The AA must establish or adopt the DSHS Payer of Last Resort policy for agencies in their region.</p> <p>Agencies providing EFA medications must develop policies and procedures to pursue all feasible alternative revenues systems (e.g., pharmaceutical company patient assistance programs) before requesting reimbursement through EFA.</p>
<p><b>Cost efficient form of medication</b></p>	<p>The AA must establish MOU/MOA with local dispensing pharmacies to ensure that prescriptions are filled at the most cost-efficient price.</p>

## Standards of Care

<p><b>LPAP Program</b></p> <p>Implement a Local AIDS Pharmaceutical Assistance Program (LPAP) for the provision of HIV/AIDS medication using a drug distribution system that is consistent with the most current HIV/AIDS Treatment Guidelines</p>	<p>The AA will establish a Local AIDS Pharmaceutical Assistance Program for providers within their region.</p> <p>Elements of the Program must include:</p> <ul style="list-style-type: none"> <li>-A client enrollment and eligibility determination process for Ryan White/state services funding that includes screening/applying for ADAP</li> <li>Additional LPAP eligibility (i.e. financial criteria) if applicable</li> <li>-A LPAP advisory board</li> <li>-Uniform benefits for all enrolled clients throughout the region</li> <li>-Compliance with Ryan White requirement of payer of last resort</li> <li>-A recordkeeping system for distributed medications</li> <li>-A drug distribution system that includes a drug formulary approved by the LPAP Board or a subcommittee of a Planning Council/ADAP - Advisory Board</li> <li>-All medications have to be FDA approved</li> <li>-A system for drug therapy management</li> </ul>
<p><b>LPAP Advisory Board</b></p>	<p>The AA shall establish a formal LPAP Advisory Board. At minimum, there must be an established advisory board in an HSDA where LPAP funding is allocated</p> <ul style="list-style-type: none"> <li>-There may not be more than one (1) advisory board in a single HSDA to ensure uniform LPAP benefits within the HSDA.</li> <li>-A single advisory board may serve multiple HSDAs.</li> <li>-An advisory board may not be comprised solely of employees of the agency/agencies funded to provide LPAP services.</li> <li>-The AA shall support the advisory board to ensure actions taken by the board are documented and are in compliance with applicable standards of care and State and Ryan White HIV/AIDS Program requirements.</li> <li>-An AA, with a written agreement between the AA and the AA of another service area, may use an established LPAP advisory board in another HSDA or Part A jurisdiction to meet LPAP requirements (sample agreement in Attachment 1).</li> </ul>

<b>LPAP Formulary</b>	<p>The AA must maintain a published formulary listing the medications approved by the LPAP Advisory Board</p> <ul style="list-style-type: none"> <li>-The formulary must at minimum meet the requirements listed in the Standards of Care.</li> <li>-The formulary must be readily accessible to providers, clients and other stakeholders</li> <li>-There must be a formalized policy and procedure for medications to be added to, or removed from, the LPAP formulary by the advisory board.</li> </ul>
<b>Medication Deductibles, and/or Dispensing Fee</b>	<p>Agencies may use funding to assist eligible clients with purchasing medications that are over the Medicaid monthly allotment or that the TMHP program does not cover.</p> <ul style="list-style-type: none"> <li>-Agencies may charge clients with a FPL above 100% a co-payment for medication based on an established sliding fee scale.</li> <li>-Agencies may charge a dispensing fee.</li> </ul>
<b>Timeliness of Service</b>	<p>Agencies will develop policies/procedures to:</p> <ul style="list-style-type: none"> <li>-Provide access to its system of drug reimbursement for clients with HIV/AIDS through Memorandums of Understanding (MOUs) or Memorandums of Agreement (MOAs) with local pharmacies</li> <li>-Implement a system for clients to access prescriptions twenty-four (24) hours/day if feasible</li> <li>-Provide mechanisms for urgent and/or emergency care.</li> <li>-Determine amount of time between ordering of the medication by the provider and prescription availability to the client.</li> </ul>
<b>Over the Counter (OTC) medications</b>	<p>LPAP can pay for over-the-counter medications if the provider has deemed that the medication is needed for prevention and treatment of opportunistic infections or to prevent the serious deterioration of health and the medication is on the formulary.</p> <ul style="list-style-type: none"> <li>-Provider must issue a prescription for the over-the-counter medication or a signed document approving use by the patient.</li> </ul>
<b>Agency Documentation</b>	<p>Agency shall provide and maintain accurate program record keeping, including medication inventory control.</p>

<b>Client Documentation</b>	<p>Eligibility determination will be kept on file in the primary client record system.</p> <p>Copies of receipt(s) for payment will be kept on file.</p> <p>Documentation in the client's primary record must include the attempts made to access client assistance programs with pharmaceutical companies, private or public insurance programs the client may have and other community resources.</p>
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## **Attachment 1**

### ***Letter of Agreement***

#### ***Local Pharmacy Assistance Program (LPAP)***

The [“Requesting Administrative Agency”] and the [“Administrative Agency with an LPAP”] agree to the following with regard to the implementation of a Local Pharmacy Assistance Program for the [Name of HIV Service Delivery Area(s) (HSDAs)]:

#### **Purpose of Agreement:**

The purpose of a Local AIDS Pharmaceutical Assistance Program (LPAP) is to provide therapeutics to treat HIV/AIDS or to prevent the serious deterioration of health arising from HIV/AIDS in eligible individuals, including measures for prevention and treatment of opportunistic infections. An LPAP is a program to ensure that clients receive medications when other means to procure medications are unavailable or insufficient. As such, LPAPs are meant to serve as an ongoing means of providing medications for a period of time. Texas Department of State Health Services (DSHS) LPAP Standards of Care require an Administrative Agency (AA) allocating funds to the local pharmacy assistance service category in an HSDA under their jurisdiction to, among other requirements, establish a formal LPAP Advisory Board and publish an approved Formulary of medications allowable to be provided through the LPAP.

This agreement stipulates that the [“Requesting Administrative Agency”] shall rely on the already established LPAP Advisory Board and published LPAP formulary of the [“Administrative Agency with an LPAP”] which is supported to function as the LPAP advisory board for the [Name of HSDA(s)].

#### **[“Requesting Administrative Agency”] and the [“Administrative Agency with an LPAP”] agree to the following conditions and stipulations regarding the agreement:**

- This agreement is expressly limited to the reliance by [“Requesting Administrative Agency”] on the already established LPAP advisory board and formulary in order for [“Requesting Administrative Agency”] to meet Health Resources Services Administration (HRSA) Ryan White HIV/AIDS Program LPAP requirements;
- [“Administrative Agency with an LPAP”] shall not incur cost or liability with respect to [“Requesting Administrative Agency”] meeting its contractual obligations to DSHS;
- [“Requesting Administrative Agency”] shall not provide funding towards the support of the already established LPAP advisory board;
- [“Administrative Agency with an LPAP”] agrees to share the most current list of medications approved by the LPAP Advisory Board with the [“Requesting Administrative Agency”];
- [“Administrative Agency with an LPAP”] will include [“Requesting Administrative Agency”] to the extent feasible when convening LPAP advisory board meetings.



["Administrative Agency with an LPAP"] will promptly notify ["Requesting Administrative Agency"] of changes made to the formulary by the LPAP advisory board;

- ["Requesting Administrative Agency"] may participate in the ["Administrative Agency with an LPAP"] LPAP advisory board to the extent feasible;
- ["Requesting Administrative Agency"] shall follow the same procedure as other stakeholders with respect to requesting the LPAP advisory board to add medications to the formulary. The decisions of the LPAP advisory board with respect to adding or removing medications from the formulary shall be binding upon ["Requesting Administrative Agency"] except as noted below;
- ["Requesting Administrative Agency"] may, when clinically indicated, supplement the published LPAP formulary by adding otherwise allowable medications to the LPAP formulary for the HSDA(s) administered by ["Requesting Administrative Agency"]. Such additions shall not be binding on the ["Administrative Agency with an LPAP"] LPAP formulary;
- ["Name of Requesting Administrative Agency"] may, when appropriate, further restrict medications on the approved LPAP formulary for the HSDA(s) administered by ["Name of Requesting Administrative Agency"]. Such restrictions shall not be binding on ["Administrative Agency with an LPAP"] LPAP formulary;
- This agreement shall be reviewed annually by all parties and updated as needed;
- Any party to this agreement may terminate the agreement by giving thirty (30) day written notice to the other parties.

Agreed to this date by:

["Requesting Administrative Agency"]

\_\_\_\_\_  
Name & Title

\_\_\_\_\_  
Date

["Administrative Agency with an LPAP"]

\_\_\_\_\_  
Name & Title

\_\_\_\_\_  
Date

## References

Panel on Antiretroviral Guidelines for Adults and Adolescents. Guidelines for the use of antiretroviral agents in HIV-1-infected adults and adolescents. Department of Health and Human Services. Available at <http://www.aidsinfo.nih.gov/ContentFiles/AdultandAdolescentGL.pdf>. July 14, 2016.

HRSA/HAB Division of Service Systems Program Monitoring Standards – Part A April, 2013, page 6-7.

HRSA/HAB Division of State HIV/AIDS Programs National Monitoring Standards – Program Part B April, 2013, page 6-7.

HRSA HAB Local Pharmaceutical Assistance Programs (LPAPs): Update and clarifications. December 2013.

HRSA HAB Local Pharmaceutical Assistance Program (LPAP) FAQs · LPAP Policy Clarification Memo (8/29/13)

Texas Administrative Code: TAC 22, Chapter 15, 291.6

Texas Department of State Health Services HIV/STD Program Policies. Payer of Last Resort (Policy 590.001). Located at <http://www.dshs.state.tx.us/hivstd/policy/policies.shtm>

Texas Department of State Health Services HIV/STD Program Policies Purchasing Prescription or Over-The-Counter Medications and Vitamins not Covered by a Third-Party Payer. (Policy 220.101). Located at <http://www.dshs.state.tx.us/hivstd/policy/policies.shtm>

Texas Department of State Health Services HIV/STD Program Policies HIV/STD Medication Program Pharmacy Eligibility Criteria. (Policy 700.003) Located at <http://www.dshs.state.tx.us/hivstd/policy/policies.shtm>